250 parts per million of the sodium carbonate. Such sodium carbonate is used or intended for use in potable water systems to reduce hardness and aid in sedimentation and coagulation by raising the pH for the efficient utilization of other coagulation materials.

(2) As an anticaking agent in sodium nitrite at a level not in excess of 0.1 percent by weight thereof for authorized uses in cured fish and meat.

(c) In addition to the general labeling requirements of the Act:

(1) Sodium carbonate produced in accordance with paragraph (b)(1) of this section shall be labeled to show the presence of the additive and its label or labeling shall bear adequate directions for use.

(2) Sodium nitrite produced in accordance with paragraph (b)(2) of this section shall bear the labeling required by §172.175 and a statement declaring the presence of sodium mono- and dimethyl naphthalene sulfonates.

[42 FR 14491, Mar. 15, 1977, as amended at 63 FR 7069, Feb. 12, 1998]

§ 172.826 Sodium stearyl fumarate.

Sodium stearyl fumarate may be safely used in food in accordance with the following conditions:

(a) It contains not less than 99 percent sodium stearyl fumarate calculated on the anhydrous basis, and not more than 0.25 percent sodium stearyl maleate.

(b) The additive is used or intended for use:

(1) As a dough conditioner in yeast-leavened bakery products in an amount not to exceed 0.5 percent by weight of the flour used.

(2) As a conditioning agent in dehydrated potatoes in an amount not to exceed 1 percent by weight thereof.

(3) As a stabilizing agent in nonyeast-leavened bakery products in an amount not to exceed 1 percent by weight of the flour used.

(4) As a conditioning agent in processed cereals for cooking in an amount not to exceed 1 percent by weight of the dry cereal, except for foods for which standards of identity preclude such use.

(5) As a conditioning agent in starch-thickened or flour-thickened foods in an amount not to exceed 0.2 percent by weight of the food.

§ 172.828 Acetylated monoglycerides.

The food additive acetylated monoglycerides may be safely used in or on food in accordance with the following prescribed conditions:

(a) The additive is manufactured by:

(1) The interesterification of edible fats with triacetin and in the presence of catalytic agents that are not food additives or are authorized by regulation, followed by a molecular distillation or by steam stripping; or

(2) The direct acetylation of edible monoglycerides with acetic anhydride without the use of catalyst or molecular distillation, and with the removal by vacuum distillation, if necessary, of the acetic acid, acetic anhydride, and triacetin.

(b) The food additive has a Reichert-Meissl value of 75–200 and an acid value of less than 6.

(c) The food additive is used at a level not in excess of the amount reasonably required to produce its intended effect in food, or in food-processing, food-packing, or food-storage equipment.

[42 FR 14491, Mar. 15, 1977, as amended at 50 FR 3508, Jan. 25, 1985]

§ 172.829 Neotame.

(a) Neotame is the chemical *N*-[*N*-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine-1-methyl ester (CAS Reg. No. 165450–17–9).

(b) Neotame meets the following specifications when it is tested according to the methods described or referenced in the document entitled ''Specifications and Analytical Methods for Neotame'' dated April 3, 2001, by the NutraSweet Co., 699 North Wheeling Rd., Mount Prospect, IL 60056. The Director of the Office of the Federal Register has approved the incorporation by reference of this material in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., rm.

1C–100, College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(1) Assay for neotame, not less than 97.0 percent and not more than 102.0 percent on a dry basis.

(2) Free dipeptide acid (*N*-[*N*-(3,3-dimethylbutyl)-L-α-aspartyl]-L-phenylalanine), not more than 1.5 percent.

(3) Other related substances, not more than 2.0 percent.

(4) Lead, not more than 2.0 milligrams per kilogram.

(5) Water, not more than 5.0 percent.

(6) Residue on ignition, not more than 0.2 percent

(7) Specific rotation, determined at 20 °C $[\alpha]_D$: −40.0° to 43.4° calculated on a dry basis.

(c) The food additive neotame may be safely used as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice, in an amount not to exceed that reasonably required to accomplish the intended technical effect, in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(d) When neotame is used as a sugar substitute tablet, L-leucine may be used as a lubricant in the manufacture of tablets at a level not to exceed 3.5 percent of the weight of the tablet.

(e) If the food containing the additive purports to be or is represented to be for special dietary use, it shall be labeled in compliance with part 105 of this chapter.

[67 FR 45310, July 9, 2002]

§ 172.830 Succinylated monoglycerides.

The food additive succinylated monoglycerides may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a mixture of semi- and neutral succinic acid esters of mono- and diglycerides produced by the succinylation of a product obtained by the glycerolysis of edible fats and oils, or by the direct esterification of glycerol with edible fat-forming fatty acids.

(b) The additive meets the following specifications:

Succinic acid content: 14.8%–25.6%
Melting point: 50 °C–60 °C.
Acid number: 70–120

(c) The additive is used or intended for use in the following foods:

(1) As an emulsifier in liquid and plastic shortenings at a level not to exceed 3 percent by weight of the shortening.

(2) As a dough conditioner in bread baking, when such use is permitted by an appropriate food standard, at a level not to exceed 0.5 percent by weight of the flour used.

§ 172.831 Sucralose.

(a) Sucralose is the chemical 1,6-dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside (CAS Reg. No. 56038–13–2).

(b) The additive meets the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 398–400, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Product Policy (HFS–206), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(c) The additive may be used as a sweetener in foods generally, in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect.

(d) If the food containing the additive purports to be or is represented to be